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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,292	03/21/2001	De-Chao Yu	348022001500	4803

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT PAPER NUMBER

1636

DATE MAILED: 11/05/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/814,292	Applicant(s) YU ET AL.	
	Examiner Gerald G Leffers Jr.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 October 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 54, 56, 58-61, 63-70, 72-76, 78-83 and 104-107 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 54, 56, 58-61, 63-66, 70, 72-76, 78-83 and 104-107 is/are rejected.
- 7) ☐ Claim(s) 67-69 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>12, 13</u> . | 6) <input type="checkbox"/> Other:  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I (claims 1-50, 54-83, 96-97 and 103) in Paper No. 15 (filed 8/1/02) is acknowledged. Several claims were amended in Paper No. 15, several claims were cancelled (claims 6-53, 55, 57, 62, 71, 77, 84-103) and new claims were added (claims 104-107). Claims 1-5, 54, 56, 58-61, 63-70, 72-76, 78-83 and 104-107 are pending in this application.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 82-83 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Each of the claims is directed towards "[a] host cell" comprising an adenoviral vector of the invention. The specification describes the host cell of the invention as encompassing cells in vivo that have been transfected with an adenoviral vector of the invention (page 23, lines 16-21). The specification teaches that the adenoviral vectors of the invention can be used to treat humans. Thus, a reasonably broad interpretation of the claim language embraces cells within a human that have been infected with an adenoviral vector of the invention. Therefore, the claims can be read to encompass a human, which is NON-STATUTORY subject matter.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54, 56, 58-63, 66, 70, 72-83, 104-107 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed towards adenoviral vectors comprising an adenoviral gene essential for replication under transcriptional control of a uroplakin II (UPII) transcriptional response element (TRE). The specification teaches that the term "transcriptional response element" refers to a promoter or enhancer that increases transcription of an operatively linked polynucleotide sequence (page 14, lines 13-18). A reasonably broad interpretation of the words "uroplakin II TRE" encompasses homologs of the human or murine regulatory elements taught in the instant specification that are obtained from alternative sources (e.g. camel, kangaroo, etc.). In addition, since the term "TRE" encompasses any enhancer element that regulates expression of the uroplakin II gene under any conditions from any source (including human and mouse), there are potentially additional transcriptional regulatory elements (TREs) that are not homologous to those described in the specification (i.e. SEQ ID NOS: 1-2). Therefore, the rejected claims encompass a very large number of potential TRE sequences.

The specification teaches only two sequences from two different sources that are considered to be TRE sequences associated with uroplakin II genes (i.e. from human and

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mouse). The specification does not provide a basis for one to extrapolate structural/functional characteristics of these sequences to other potential TRE sequences associated with uroplakin II genes obtained from alternative sources. The specification does not provide a basis for one to extrapolate structural/functional characteristics of these sequences to other potential TRE sequences associated with the human and mouse uroplakin II genes that act to increase expression of the uroplakin II genes during different conditions (e.g. during different stages of animal development).

The prior art does not appear to teach the characterization of all of the human and/or mouse uroplakin II TRE elements that are required for expression under different conditions (e.g. during embryonic development, old age, etc.). The prior art does not appear to teach TRE elements from uroplakin II genes from alternative mammalian sources. Therefore, the prior art does not offset the deficiencies of the instant specification with regard to describing the broadly claimed genus of TRE elements.

Given the very large number of potential uroplakin II TRE sequences encompassed by the rejected claims and give the lack of a basis provided by the instant specification or prior art for envisioning TRE elements associated with uroplakin II genes that are not homologous to the human or mouse sequences described in the specification, one of skill in the art would not have been able to envision a representative number of specific embodiments to describe the broadly claimed genus of such uroplakin II TRE sequences. Therefore, one of skill in the art would have reasonably concluded that applicants were not in possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-5, 56, 58-61, 63-65, 78-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds in that it recites "2028" and "2239" without reference to any units. It would be remedial to amend the claim so that the terms refer to "nucleotides".

Claims 1-5, 64-65 are vague and indefinite in that the metes and bounds of the term "comprising about" in reference to polynucleotide positions within SEQ ID NOS: 1-2 are unclear. How far away from the specified nucleotides can a sequence comprised within a nucleic acid of the invention be and still satisfy the criteria of being "comprising about". For example, in claim 1, can a nucleic acid comprising a UPII element comprising polynucleotides 2038-2229 of SEQ ID NO: 1 satisfy the limitations of "about 2028 to about 2239 of SEQ ID NO: 1"?

Claim 56 and 61 are vague and indefinite in that there is no clear and positive prior antecedent basis for the words "the adenoviral gene". It would be remedial to amend the claim language to read "the adenoviral gene essential for replication".

Claims 63 and 66 are vague and indefinite in that the claims are directed towards claim 62, which has been cancelled. It would be remedial to amend the claims to depend upon a pending claim, or to include all of the claim limitations of the cancelled claim upon which they are currently dependent.

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Claims 63, 66 and 78-79 are vague and indefinite in that the nature and number of steps required to construct a TRE "derived" from a uroplakin II gene are unclear. It would be remedial to change the word "derived from" to "obtained from".

***Conclusion***

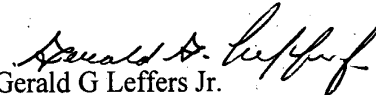
No claims are allowed. Claims 1-5, 54, 56, 58-61, 63-70, 72-76, 78-83 and 104-107 are pending in the application. Claims 67-69 are objected to as being dependent upon a rejected claim, but would be allowable if rewritten to comprise each of the limitations of the claim upon which they are currently dependent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232.

The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Gerald G Leffers Jr.  
Examiner  
Art Unit 1636

ggl  
November 3, 2002